Department of Veterans Affairs Quality Enhancement Research Initiative (QUERI)

Diabetes QUERI Center 2008 QUERI Strategic Plan

December 2008



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Part I. Diabetes QUERI Center Mission, Goals and Scope

I.1 Clinical Focus and Scope

Diabetes mellitus is a chronic condition characterized by elevated glucose levels (i.e., hyperglycemia) due to the body's inability to use blood glucose for energy. There are several different types of diabetes but the primary form that affects patients in the VA is type 2 diabetes. Type 2 diabetes, which is most likely to develop in middle-aged and older adults, results either because the pancreas is not producing enough insulin (which is needed to metabolize blood glucose), or the body is not able to use insulin correctly. While there may be some VA patients with type 1 diabetes, a condition in which the pancreas is no longer making any insulin, this number is very low since type 1 diabetes generally develops in younger people and would exclude someone from military service.

Among people with diabetes, the presence of specific risk factors over time can lead to severe and devastating end organ complications including blindness, end-stage renal disease, amputation, heart attack and stroke. These risk factors include persistently elevated glucose levels, poorly controlled hypertension and dyslipidemia. Appropriate treatment of these risk factors along with the early recognition and treatment of foot ulcers, retinal disease, and renal impairment are known to be successful in reducing end organ complications. Consequently, the Diabetes QUERI is committed to research and collaborations with key VA and non-VA partners to promote the use of effective care strategies that will decrease the number of patients who experience these complications and thereby help veterans with diabetes live longer and better lives.

Additionally, preventing type 2 diabetes through lifestyle changes and the use of medication in persons at high-risk for developing diabetes, as demonstrated in the U.S. Diabetes Prevention Project (DPP) and Finnish Diabetes Prevention Study (DPS), (Kohner et al., 2001; Lindstrom et al., 2003) is also of great interest to the Diabetes QUERI. Although practical approaches for implementing these findings on a population-wide basis are still being developed we have several projects, both planned and underway, that involve potentially promising strategies to help prevent type 2 diabetes. Specifically, in collaboration with the VA National Center for Health Promotion and Disease Prevention we are developing and testing interventions to promote weight loss and increase physical activity for patients with or at risk for diabetes.

The primary focus of the Diabetes QUERI is on veterans with diabetes or veterans who may be at risk for diabetes. But because the prevalence of other chronic conditions is quite high

among veterans with diabetes, we are also very interested in the effective management (including both care delivery and self-management) of patients with multiple major co-morbid conditions. Our work in this area spans a broad range of co-morbid conditions (cardiovascular disease, chronic pain, depression) and provides an opportunity for collaborating with other QUERI groups.

I.2 Significance and Consequences: Epidemiology, Morbidity/Mortality, Quality of Life and Costs

Diabetes is an extremely prevalent condition whose health and economic consequences have tremendous impact. According to estimates from the Centers for Disease Control and Prevention (CDC), diabetes affects nearly 24 million people in the U.S. or 8% of the general U.S. population (CDC 2007). The prevalence is considerably higher in VA, however, with diabetes affecting nearly 20% of veterans who use the VA health care system or over one million VA patient users at any given time (Miller et al., 2004) (VA Fact Sheet, VA Achievements in Diabetes Care, February 2006). Furthermore, the number of individuals with diabetes appears to be on the rise worldwide, attributable in part to the aging population and other general risk factors including obesity and sedentary life-styles. In VA the number of individuals receiving care for diabetes is also likely to increase. In addition to the factors listed above, this increase is the result of a policy change that added type 2 diabetes to the list of presumptive conditions associated with herbicide exposure, including Agent Orange. Rules permitting eligible veterans to apply for and receive compensation for type 2 diabetes went into effect July 9, 2001.

Diabetes is a leading cause of blindness, end stage renal disease, and amputation in the U.S. (American Diabetes Association 2008a) and in the VA, with at least three quarters of non-traumatic amputations in VA involving patients with diabetes (Mayfield et al., 2004). The mortality rate among VA patients with diabetes averages approximately 5% per year, compared with an average of 2.6% among patients without diabetes (Miller et al., 2004). The majority of deaths and hospitalizations related to diabetes, both inside and outside VA, are due to macrovascular complications such as heart attack and stroke (Snow et al., 2003; Engelgau et al., 2004; Vijan et al., 2004).

Also of note is the proportion of patients with diabetes who have other chronic co-morbid conditions. Multi-morbidity is a ubiquitous problem among the VA patient population. One study found that veterans who had one or more primary care visits had on average 3.5 chronic illnesses (Hitchcock 2003). Another study, by Dr. Gayle Reiber (a member of the Diabetes QUERI Executive Committee) and colleagues, found that among a cohort of VA patients with

diabetes who received care in FY1998, 67% also had a diagnosis of hypertension, 41% had coronary artery disease, 15% had chronic obstructive pulmonary disease and 12% had depression (Reiber et al., 2004).

In 2007, the total estimated cost of diabetes was \$174 billion (American Diabetes Association 2008b). On average, medical expenditures for people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes. Medical costs attributed to diabetes included \$27 billion for care for the direct treatment of diabetes, \$58 billion to treat chronic complications that are attributed to diabetes, and \$31 billon in excess general medical costs. Moreover, a study by Diabetes QUERI affiliated investigators found that costs associated with diabetes-related mortality, disability, early retirement and work absenteeism, based on a national household sample of Americans, was more than \$133 billion over the lifetime of the study cohort (Vijan et al., 2004). Aside from the staggering cost impact, this study draws attention to the increased prevalence of physical and cognitive disability among persons with diabetes, which often lead to absenteeism and early retirement. An increased risk of disability among individuals with diabetes has been found in a number of studies (Engelgau et al., 2004) and is of concern not only because of the cost implications but the impact on quality of life.

In VA, the use of inpatient hospital care provided by VA facilities for veterans with diabetes decreased from 1.68 discharges per person in 1994 to 1.61 discharges per person in 1998 (Maciejewski and Maynard 2004). At the same time, however, the use of VA outpatient care among veterans with diabetes has been on the rise. It is estimated that in FY1998, the total cost of VA inpatient and outpatient use by veterans with diabetes was over \$1.6 billion, approximately 3.9% of total VA expenditures (Maciejewski and Maynard 2004). Annual VA pharmacy costs for patients with diabetes have also been increasing. As of FY2000, VA patients with diabetes received 30% of all VA pharmacy prescriptions, which accounted for approximately 28% of all pharmacy dollars expended (Weinstock et al., 2004). Given the growing array of therapeutic options and treatment strategies to prevent or delay severe diabetes-related complications and enhance quality of life, these costs are likely to continue to grow.

I.3 Treatment/Management Evidence Base

The evidence base for optimizing diabetes care and patient outcomes is extensive and is the foundation for the VA-DoD Management of Diabetes Mellitus Clinical Practice Guidelines (Pogach, Brietzke et al., 2004), see http://www.oqp.med.va.gov/cpg/DM/DM_base.htm. The

Diabetes QUERI has a long-standing linkage to the guideline development process with Executive Committee (EC) members serving on the Diabetes Advisory Field Group (DAFG) and the VHA National Clinical Practice Guidelines Council. The fact that so much is known about how to improve outcomes for patients with diabetes is what provides the true impetus for the Diabetes QUERI, since our goal is to help implement strategies that efficiently deliver state-of-the-art evidence-based care in the VA. Due to the vast nature of the literature and because the guideline documents include a review and rating of evidence within 8 major areas (management of hypertension, management of lipids, screening and prevention, glycemic control, eye care, foot care, kidney function and self-management and education) our discussion highlights only key studies and those findings especially relevant in defining the Diabetes QUERI priority areas.

During the past decade, efficacy studies have demonstrated that improving processes of care can substantially delay or prevent both microvascular and macrovascular complications of diabetes. Microvascular disease, which affects small blood vessels in the eye, kidney and nerves, is influenced by both level of glycemic control (i.e., blood sugar control) and blood pressure control (DCCT 1993; UK Prospective Diabetes Study 1998a; UK Prospective Diabetes Study 1998b; Stratton et al., 2000; Bakris et al., 2003; Patel, MacMahon et al., 2008). Although most veterans now have at least acceptable glycemic control, patients who continue to have persistently poor control, especially those younger than 60, remain a high-risk population of interest for the Diabetes QUERI. Even among high risk patients, tight glycemic control appears not to decrease macrovascular complications (DCCT 1993; UK Prospective Diabetes Study 1998a; Abraira et al., 2008; Patel, MacMahon et al., 2008) and may actually increase overall mortality (Gerstein et al., 2008). There are, however, effective treatments (including hypertension control, treatment with lipid lowering agents, aspirin therapy) for several macrovascular risk factors and strong evidence that risk factor modification provides dramatic reductions in morbidity and mortality.

Specifically, aggressively controlling blood pressure for patients with diabetes may be the most important factor in decreasing adverse outcomes, including both macrovascular and microvascular events (Vijan and Hayward 2003). Aggressive management of blood pressure and appropriate selection of antihypertensive agents are also key elements in the prevention and management of renal complications for patients with diabetes. Moreover, work by the CDC Diabetes Cost-effectiveness Group suggests that intensified hypertension control not only improves health outcomes but is also cost-saving (C. D. C. Diabetes Cost-effectiveness Group 2002). Treatment with lipid lowering agents is another important tool to decrease the risk of cardiovascular complications among patients with type 2 diabetes, (Vijan et al., 2004) even

among those with low baseline low-density lipoprotein cholesterol (LDL) levels (Heart Protection Study Collaborative Group 2002). In both the VADT and ADVANCE trials, outcomes were better than expected, due in large part to aggressive control of other cardiovascular risk factors. These studies support our continuing focus on cardiovascular risk reduction through aggressive blood pressure treatment and statin therapy.

In addition to the benefits associated with improved glycemic control and management of cardiovascular risk factors, early detection and treatment of eye and foot complications also have proven efficacy (Vijan et al., 1997). Evidence suggests that 90% of visual loss due to diabetic retinopathy can be prevented through optimal medical (including good blood pressure and glycemic control) and ophthalmologic care, with early detection and optimally-timed laser therapy playing a key role in this prevention strategy (Early Treatment Diabetic Retinopathy Study Research 1991) However, while laser therapy for established diabetic retinal complications is an effective treatment, there has been controversy surrounding the timing of routine retinal screening. Work conducted by the Diabetes QUERI, as well as in the United Kingdom, shows that conducting routine annual screenings for most diabetes patients is inefficient (as the majority of those undergoing frequent examinations are patients with previously normal fundoscopic examinations) and closer monitoring of those with known disease is likely more effective in preventing blindness due to diabetic retinopathy and macular edema (Vijan et al., 2000; Kohner et al., 2001; Younis et al., 2003; Hayward et al., 2005). In recent years, VACO Patient Care Services has placed increasing emphasis upon the provision of tele-retinal non-mydriatic screening in primary care, especially in rural areas, which has increased adherence to screening (Conlin et al., 2006).

It is estimated that up to 50% of amputations are preventable (Technical Advisory Committee for Diabetes Translation and Community Control Programs 1992), with a number of observational, quasi-experimental and randomized controlled studies to show that foot complication rates can be substantially reduced through the use of certain practices (Litzelman et al., 1993; Singh et al., 2005). Decreasing ulcers and amputation requires a coordinated, multidisciplinary systems approach that includes screening, surveillance and salvage (Wrobel et al., 2003). However, despite VA Directives to field these multidisciplinary approaches, such programs are variably implemented within VHA (Pogach, Charns et al., 2004). Moreover, research (including a study by Diabetes QUERI affiliated investigators) also suggests that the application of specific clinical practices in isolation (e.g., educating patients to inspect their feet on a daily basis) is not enough. Finally, a recent publication indicates that despite adequate "knowledge", patient adherence to recommended foot care practices is generally poor, and

varies among facilities (Rajan et al., 2007). These observations have resulted in the development of a Patient Care Services High Risk Foot Clinical Cohort, linked to the PACT Directive (2008 revision), to facilitate a systematic approach to identifying high risk patients whose care lacks continuity and who are not receiving primary care or specialty care within VA. Outreach can then be provided to these patients.

Patient adherence to recommended foot care practices is merely one aspect of the self-care required of patients with diabetes, a lifelong, complex and intrusive disease. This arena of care is generically referred to as "self-management" and includes taking medications, following nutrition and exercise plans, and monitoring disease control. There is some evidence explicitly linking good self-management to better diabetes outcomes (Heisler et al., 2003), but it is also fairly well established that patients who do not adhere to treatment tend to have poorer health outcomes. For this reason, self-management is one of Diabetes QUERI's priority areas, including work in the areas of medication adherence, physical activity and obesity prevention and treatment, which is central to both diabetes prevention and management.

Another treatment issue related to the mission of Diabetes QUERI is the inpatient management of glycemic control. There are several studies suggesting survival benefits and decreased morbidity with intensive glucose monitoring and management of critically ill and post-surgical patients (Malmberg 1997; Malmberg et al., 1999; van den Berghe et al., 2001; Trence et al., 2003) but the evidence is still evolving. Moreover, a systematic review of inpatient hyperglycemia management by the Portland Veterans Affairs Healthcare System Oregon Evidence-based Practice Center found that the benefits of trying to achieve normal blood sugar levels in critically ill patients through the use intensive insulin therapy are not clear and the practice is associated with high rates of hypoglycemia

(http://www.hsrd.research.va.gov/publications/esp/Hyperglycemia-2008.pdf). In addition, while more moderate blood glucose control targets can be achieved in a safer manner (with the avoidance of both high levels of hyperglycemia <u>and</u> hypoglycemia), the benefits of this practice with respect to health outcomes have not been well studied.

I.4 Current Practices and Quality/Outcome Gaps

The quality of diabetes care in VA has been significantly improving over the past decade, and measured aspects appear to equal or even exceed the care received by some community-based populations (Jha et al., 2003; Asch et al., 2004; Kerr et al., 2004; Sawin et al., 2004). For example, the mean LDL level dropped from 111mg/dL in FY99 to 104 mg/dL in FY01, and the mean hemoglobin A1c value decreased from 8.3% in FY96 to 7.4% in FY01

(http://vaww.va.gov/haig/). Longitudinal analyses from the Diabetes Epidemiology Cohorts (DEpiC) for all VA patients with diabetes and A1c testing in 2000-2004 showed that the average A1c was 7.27% in 2000 with an overall adjusted decline of 0.06% per year, although some differences were found by race, ethnicity, and co-morbidity status (Miller DR 2008). Nonetheless, these improvements are known to translate into fewer deaths and serious complications. Recent VA Performance Reports (Office of Quality and Performance 2007) show that 84% of VA diabetes patients had an LDL < 130mg/dl and that only 7% of patients were under very poor glycemic control (i.e., A1c > 11.0%) or had not had an A1c measured in FY07.

Moreover, a Diabetes QUERI study (TRIAD-VA), conducted in collaboration with the CDC, compared VA with several top performing commercial managed care (CMC) plans, and found that VA patients had better scores than CMC patients on key process measures, ranging from a 10 percentage point difference on performance of an annual A1c (93% versus 83%; p=0.006) to a 25 percentage point difference on aspirin use counseling (74% versus 49%; p<0.001). VA patients also had better control of LDL and A1c (86% versus 72% for LDL<130 mg/dl, p=0.002; 92% versus 80% for A1c<9.5%, p=0.006). There was no difference in blood pressure control between VA and CMC participants but the level of control was generally poor in both groups (Kerr et al., 2004). Another published study also shows that diabetes care in VA is better than that received by a comparable community sample (Asch et al., 2004).

Despite these positive results, there is still room for improvement, especially in the areas of blood pressure control, foot care, kidney disease and self-management. Blood pressure control is critical in decreasing both micro- and macro-vascular complications, but the rate of control remains suboptimal. Projects conducted by the Diabetes QUERI have identified gaps in blood pressure control related to both patient-specific factors as well as provider related factors, including how physicians identify treatment priorities, clinical uncertainty about a patient's true BP value, and competing demands (Hofer et al., 2004; Subramanian et al., 2007; Heisler et al., 2008; Kerr, Zikmund-Fisher et al., 2008). As such, Diabetes QUERI is actively engaged in projects to improve care by understanding and targeting interventions at both the patient and provider levels.

Along with continuing opportunities for improving patient intermediate outcomes, such as blood pressure levels, there are a number of areas in which the Diabetes QUERI has also identified a need for additional intervention to prevent disabling complications. For example, increases in diabetes foot screening measures (e.g., visual inspection, monofilament testing) have been observed over the past several years along with some decrease in amputation rates.

However, how much of the decrease is associated with better screening is not known. In addition, studies conducted by the Diabetes QUERI Clinical Coordinating Center (CCC) suggest an association between mental health functioning and major amputations (Tseng et al., 2007) as well as emphasize the impact of dual-system utilization (e.g., through Medicare coverage and VA) when assessing amputation outcomes in VA (Tseng et al., 2004). Such dual system use is not only likely to complicate the management of high risk patients but also makes it difficult to accurately assess the quality of care in VA using measures such as amputation rates. Based on this work, along with the findings from the "Impact of a Quality Management Intervention upon Foot Care Outcomes" project, we feel that additional strategies are required to successfully improve high-risk foot care, with the ultimate goal of preventing or minimizing lower-extremity amputations. Fortunately, the Diabetes QUERI has investigators with considerable expertise in this area who are involved with both the implementation and evaluation of promising strategies for providing good wound care for patients with diabetes.

IWe are also learning more about the prevalence, outcomes and management of chronic kidney disease (CKD), another important complication among VA patients with diabetes. Work conducted at the Diabetes QUERI Clinical Coordinating Center found a crude prevalence of CKD of 32% by calculating an estimated glomerular filtration rate (eGFR) for a national, retrospective cohort of veterans with diabetes. One study suggests that among veterans with diabetes who received VA outpatient care in FY1998, over 10% had a diagnosis of renal disease and mortality was higher for these patients than for with those without renal disease (Young et al., 2004). Additional studies from the QUERI Clinical Coordinating Center indicate that continuity of nephrology care decreased pre-dialysis mortality and progression to dialysis in veterans with stage 3-4 CKD (Tseng, Kern, Miller et al., 2008); minorities were at greatest risk (Tseng, Kern, Maney et al., 2008). Other analyses conducted both by the Clinical Coordinating Center (Tseng, Kern, Miller et al., 2008) and the Research Coordinating Center (RCC), have identified several potential areas for improving care for these patients, including better use of nephrology consultations and cardio-vascular medications (e.g., ACE-I and ARBs) in collaboration with Patient Care Services (Patel, Pogach et al., 2008).

In addition to enhancing efforts to prevent and better manage the major clinical sequelae of diabetes, much work also remains in helping patients adopt routine diabetes self-management activities. One Diabetes QUERI study showed that better self-management is associated with improved glycemic control (Heisler et al., 2003) and may lead to improvements for other outcomes as well. However, projects conducted by Diabetes QUERI and others have also identified a number of opportunities for improving self-management, including patient

understanding of targets and goals, appropriate use of medications and significant gaps in the area of weight management, physical activity and exercise.

For example, findings from the DQIP project, conducted by the Diabetes QUERI research and clinical coordinators in collaboration with the Office of Quality and Performance, showed that approximately 20% of surveyed veterans with diabetes did not understand how to make food choices, what their target glucose levels should be or how to exercise appropriately. Furthermore, results from a study conducted by a QUERI-affiliated investigator at the VA Puget Sound found that while most VA patients with type 2 diabetes and an A1c of 8% or greater reported receiving advice from physicians regarding physical activity, nutrition, and glucose monitoring (73%, 92%, and 98%, respectively), many were not ready to change selfmanagement behaviors (Nelson et al., 2007). Forty-five percent reported non-adherence to medications, 42% ate a high-fat diet, and only 28% obtained either moderate or vigorous physical activity. Improving the level of physical activity and exercise for this population is increasingly important given its many potential benefits, ranging from diabetes prevention to improved glycemic control, weight control and perhaps even positive effects on functional ability, psychological well-being and general quality of life. The study also found that individuals with higher self-efficacy scores were more likely to adhere to medications, follow a diabetic meal plan, eat a lower fat diet, have higher levels of physical activity, and monitor their blood sugars (P < .001 for all). This suggests that targeted patient-centered interventions may need to emphasize increasing self-efficacy and readiness to change to further improve VA diabetes outcomes, and some of our intervention studies focus on those areas.

Finally, as described in section I.2, multi-morbidity is a substantial problem in the VA patient population in general, as well as in VA patients with diabetes. Some co-morbid conditions, such as chronic pain and depression, may create significant challenges both in care delivery and self-management, thereby increasing the risk of poorer health outcomes (Piette et al., 2004). For example, a study conducted at the Diabetes QUERI research coordinating center found that approximately 60% of VA diabetes patients surveyed reported experiencing chronic pain (Krein et al., 2005). Even after adjusting for the presence of depressive symptoms and general health status, patients with diabetes and chronic pain had significantly poorer diabetes self-management overall and more difficulty with specific activities such as exercise and following a recommended eating plan. In addition to affecting patient self-management, Diabetes QUERI investigators have found that discussing pain at a primary care visit competed with medication intensification for elevated blood pressure among patients with diabetes (Kerr, Hofer et al., 2008). The predicted probability of intensification when pain was discussed was

significantly lower than when pain was not discussed (35% vs. 45%, p=0.03), while discussions of other discordant conditions or concordant conditions were not associated with likelihood of medication intensification.

I.5 Significant Influences on Current Practices and Outcomes

The significant improvements in diabetes care observed over the past several years are undoubtedly due to the combined efforts of many within VA. In particular, programs and initiatives of Patient Care Services (PCS), the performance monitoring activities by the Office of Quality and Performance (OQP) and the development and dissemination of the diabetes clinical guidelines are notable among these efforts. Research by HIV QUERI, Diabetes QUERI and other investigators suggests that EPRP measurement is a critically important tool for improving care (Asch et al., 2004), thus underscoring the importance of continuing our close partnership with OQP (Kerr et al., 2001; Kerr et al., 2003). As part of our collaborative work, OQP is currently considering testing measures we have previous developed in an effort to field more clinically meaningful measures which may go beyond those developed by non-VA organizations such as NCQA.

In addition, changes in technology and the Office of Information have helped tremendously by providing a platform to facilitate information dissemination, communication and systems that better support diabetes care delivery (Kupersmith et al., 2007). Continued technologic advances (e.g., My HealtheVet and HealtheVet and patient monitoring and messaging devices) may prove to be important tools for promoting future enhancements to the quality of diabetes care throughout the VA system.

Efforts undertaken by the Diabetes QUERI, the VA's Healthcare Analysis and Information Group, Pharmacy Benefits Management (PBM) and Patient Care Services (PCS) are also noteworthy. These groups have all contributed by examining and highlighting VA diabetes care in such a way so as to draw the attention of not only internal VA stakeholders but an external audience as well. We also expect to see additional improvements in VA diabetes care related to activities taking place through PCS and other VA offices, including the VISN Support Service Center (VSSC), Office of Care Coordination and National Center for Health Promotion and Disease Prevention.

VA care has also been influenced by a number of groups outside the VA system. For example, performance measures in VA have been generally consistent with those used outside VA and in particular with the HEDIS diabetes performance measurement set. However, because of representatives such as Drs. Pogach and Hayward on committees and

subcommittees that are responsible for recommending revisions to the NCQA diabetes measures and the National Quality Forum voluntary consensus standards for diabetes, the results of Diabetes QUERI investigations are well represented in discussions of national quality monitoring efforts. Diabetes self-management education is another important part of diabetes care in VA and both Linda Haas (EC member) and John Piette (QUERI investigator) participated in a task force, convened by the American Association of Diabetes Educators and the American Diabetes Association, that reviewed and revised the National Standards for Diabetes Self-management Education (Funnell et al., 2008).

Finally, the committed VA clinicians, along with facility and VISN leaders who have developed and implemented a variety of strategies to achieve the observed improvements in care, must be commended. Too often we focus on how care can be improved and what clinicians can or should do better. However, in this case it is appropriate and worthwhile to use successful performance in many areas of diabetes care as an example of what can be achieved when a system works together and to use this success to motivate further collegial work to improve patient outcomes.

I.6 Diabetes QUERI Center Goals

The overarching goal of the Diabetes QUERI is to partner with stakeholders to implement strategies that efficiently deliver state-of-the-art evidence-based care to help veterans with diabetes live longer and better lives. Within this goal, we have been focusing and continue to focus on several specific priority areas. These priority areas include: 1) optimizing management of cardiovascular risk factors such as hypertension, to prevent cardiovascular complications and mortality; and 2) decreasing rates of diabetes-related complications, including visual loss, lower-extremity ulcers and amputation and kidney disease. The other areas identified as Diabetes QUERI priorities do not focus on specific clinical issues, such as those listed above, but cut across all facets of diabetes care in order to help us accomplish our overarching goal. These cross-cutting priority areas consist of: 1) improving patient selfmanagement; and 2) better management of patients with diabetes and other chronic co-morbid conditions. A third cross-cutting activity, which serves as both a priority area and a mechanism for addressing all of the priority areas just identified, is ongoing work by the Diabetes QUERI to advance clinically-meaningful quality/performance measurement as an important tool both for directly promoting quality improvement and for assessing the results of quality improvement interventions.

As noted above, our clinical priorities focus on preventing both cardiovascular and other diabetes-related complications. In the past, improving glycemic control was a stand-alone clinical priority area or included along with cardiovascular risk factors as a larger general priority related to patients at highest risk for poor outcomes. However, our current approach to address the problem of very poor glycemic control is through cross-cutting diabetes quality improvement interventions, such as those designed to improve self-management (e.g., Peer Support). Further, even though we are not currently working on specific interventions to address other complications of diabetes, such as kidney disease, by focusing on improving management of hypertension we are targeting the major risk factor for diabetes-related renal failure.

Lastly, an increasingly important area for the Diabetes QUERI is the prevention of not just diabetes-related complications but diabetes itself. As such, we have begun to incorporate some of the important lifestyle related aspects of diabetes prevention, such as physical activity and weight management, into several of our current projects, and expect to increase our work in this area, particularly in relation to the returning OEF/OIF population.

I.7 Plans for Achieving Diabetes QUERI Center Goals

The approach that DM QUERI is using to achieve its goal of implementing strategies that efficiently deliver state-of-the-art evidence-based diabetes care is threefold: 1) conducting research projects; 2) engaging in policy-related and service driven activities; and, 3) fostering key partnerships both inside and outside VA. The Diabetes QUERI also continues to work to improve the care and outcomes of individuals with diabetes by assisting VA investigators and VA leadership with specific information requests, providing technical consultation on diabetes-related health services and epidemiological projects, and by disseminating information on new research findings and innovative VA diabetes programs.

The current and planned projects in the Diabetes QUERI portfolio are guided by specified conceptual frameworks that are relevant to the goals of those projects. For example, the competing demands model (Jaen et al., 1994; Stange et al., 1994) and the chronic care model (Wagner et al., 2001; Bodenheimer et al., 2002b; Bodenheimer et al., 2002a) were both part of the conceptual framework used in the ABATE study. In addition to specific guiding frameworks, we use overarching frameworks to guide our implementation work. The QUERI six-step implementation guide provides an overall roadmap for designing and implementing studies that progress from, for example, diagnosing a performance gap (Step 3) to evaluating improvement programs (Steps 5/6). Rather than using separate frameworks for each QUERI step, we have developed two overarching frameworks that guide implementation to enhance the

likelihood of system-wide dissemination and long-term sustainability: (1) the Consolidated Framework for Implementation Research (CFIR); and (2) an enhanced version of RE-AIM, called RE-AIM PLUS. The CFIR is a comprehensive framework that draws from the most relevant and rigorously evaluated frameworks in the literature. It is intended to guide formative evaluations of our implementations across all QUERI steps, all stages of implementation, and various contexts. The RE-AIM framework (Glasgow et al., 2001) provides quantitative measures describing each of 5 dimensions for evaluating an intervention (Reach, Efficacy, Adoption, Implementation, and Maintenance). We developed RE-AIM PLUS to include data on why and how these dimensions vary across settings. The CFIR informs evaluation of the "I" (Implementation) and, thus is incorporated conceptually in RE-AIM PLUS.

We have three goals related to furthering the use and development of the CFIR and RE-AIM PLUS. First, the main goal is to incorporate these frameworks into most current and future projects in Diabetes QUERI to provide a comprehensive evaluation of all interventions and implementation efforts. The CFIR framework, in particular, is used to guide formative evaluations through the different stages of assessing each site before implementation, adapting the intervention to each site, real-time monitoring of implementation fidelity and progress toward outcome goals, and evaluating degree of sustainability and prospects for wider dissemination after the study is over. Second, we will continue to refine the CFIR and RE-AIM PLUS to incorporate new findings. We are especially interested in fine-tuning the definitions for each of the CFIR constructs. Previously published definitions of the important constructs have tended to be very general, making them difficult to operationalize in the research setting. Third, we hope to create an online collaborative knowledge-base (i.e. wiki) where QUERI researchers can discuss as well as contribute findings, definitions, measurement approaches, and tools and approaches for applying to new studies.

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Part II. Management Plan

This section describes the personnel, Executive Committee, organization, and management of the diabetes QUERI.

II.1 Leadership and Staffing

The Research Coordinating Center, under the direction of Dr. Eve Kerr and co-direction of Dr. Sarah Krein, is housed at the VA Ann Arbor HSR&D Center of Excellence. The Clinical Coordinating Center, under the direction of Dr. Len Pogach, is housed at the VA New Jersey Healthcare System in East Orange while the co-clinical coordinator, Dr. David Aron, is located at the Louis Stokes Cleveland VAMC. The general structure and organization of the Diabetes QUERI are described below.

As research coordinator, Dr. Kerr is responsible for overall leadership of the Diabetes QUERI Research Coordinating Center. Dr. Kerr is a nationally recognized health services researcher in the area of quality measurement and improvement for diabetes and other chronic conditions; is the principal investigator of several QUERI projects; and, is an accomplished administrator and leader. Dr. Krein, also a health services researcher, is co-director of the Diabetes QUERI Research Coordinating Center. Dr. Krein is often the initial Diabetes QUERI point of contact in assisting researchers and others throughout VA on diabetes issues. Her current focus on the role of comorbidities in diabetes management is helping to expand this priority area. Dr. Pogach, the Diabetes QUERI clinical coordinator, is actively engaged in numerous Diabetes QUERI studies and is responsible for much of the work to identify potential disparities in diabetes care. In addition, Dr. Pogach's many roles with the VHA serve to keep the Diabetes QUERI up-to-date on important clinical and operations developments and help us form the vital partnerships that we need to accomplish DM QUERI goals. For example, as the VA National Program Director for Diabetes, Dr. Pogach provides a vital link between the Diabetes QUERI and Patient Care Services. **Dr. Aron**, the co-clinical coordinator, is helping to foster second level implementation research (i.e., beyond the bedside). Given his roles at multiple levels of clinical operations and experience as both a researcher and Chief of Medical Service, he brings to DM QUERI both his expertise on how to effectively link research and clinical operations and his knowledge of clinical operations partners. He is also actively involved in QUERI-related research projects and in refining the Diabetes QUERI implementation framework.

Dr. Julie Lowery, the implementation research coordinator, is leading an effort in collaboration with co-implementation research coordinator Laura Damschroder, to develop a

comprehensive and flexible implementation framework. Dr. Lowery also participates actively in the planning and execution of the overall portfolio, with a particular focus on evaluation and planning new implementation studies. Leah Gillon, M.S.W. serves as the administrative coordinator and project manager for several Diabetes QUERI projects. Having a full time, experienced master's-level research associate allows us to manage several internal pilot projects and collaborative projects with QUERI investigators not housed in Ann Arbor, conduct new pilot projects, and carry out administrative tasks associated with Diabetes QUERI.

The Diabetes QUERI Research Coordinating Center, based in Ann Arbor, provides consultation to VHA investigators when developing proposals and during conduct of studies. In addition, the Diabetes QUERI has a number of affiliated investigators with expertise in several different areas and these investigators have active research programs that advance Diabetes QUERI priority areas. Supporting Dr. Pogach at the Clinical Coordinating Center are personnel providing data management, data analysis and other computer support. The New Jersey Clinical Coordinating Center, under the direction of Dr. Pogach, has become increasingly active in conducting secondary data analyses, with particular expertise in examining issues related to disparities and dual system use. Dr. Aron along with his team at the Cleveland Clinical Coordinating Center are also actively engaged in Diabetes QUERI projects and provide consultation on clinically oriented implementation issues.

II.2 Meetings and Communication

Internal to the Research Coordinating Center, meetings are held weekly with the research coordinators, implementation research coordinating team and the administrative coordinator (and other investigators as indicated) for purposes of developing and collaborating on pilot projects and new proposals, review of progress of projects in portfolio, and report on field-based projects. Our administrative coordinator communicates regularly with the members of the Executive Committee and affiliated investigators to get reports on progress of their projects. All coordinators and executive committee members participate in quarterly conference calls and more often as indicated, and attempt to meet face-to-face whenever practical (e.g., at the HSR&D, QUERI, or ADA meetings). The research coordinators also have frequent email, phone communication and in-person meetings with the clinical coordinators. Further, QUERI EC members, Coordinators and other experts are part of Diabetes QUERI workgroups to address specific developmental topics. These work groups started in 2008 and have covered issues surrounding application of implementation models, performance measures, and operations involvement.

II.3 Staff and Executive Committee Roster

A current list of the Diabetes QUERI leadership and key staff, Executive Committee members, and the affiliated Diabetes QUERI investigators is included in each year's annual report. The Diabetes QUERI Executive Committee consists of individuals with diabetes research and clinical expertise and includes members from key stakeholder groups within VHA. We continually look for opportunities to expand Diabetes QUERI linkages in order to bring new ideas and inspiration to the Diabetes QUERI functions. We view the role of the Executive Committee as vitally important for generating project ideas, keeping us informed of new developments in the clinical, operations and research worlds, creating bridges to other organizations and stakeholders, and accomplishing the research mission of the Diabetes QUERI.